FEB 2 5 2003

510(K) SUMMARY
OF SAFETY AND EFFECTIVENESS

Jax™

In accordance with the Food and Drug Administration Rule to implement provisions of the Safe Medical Devices Act of 1990 and in conformance with 21 CRF 807, this information serves as a Summary of Safety and Effectiveness for the use of Jax™.

Submitted By:	Smith & Nephew, Inc. Orthopaedic Division 1450 Brooks Road Memphis, TN 38116
Date:	February 23, 2001
Contact Person:	Kim P. Kelly Senior Regulatory & Clinical Affairs Specialist
Proprietary Name:	Jax™
Common Name:	Bone Void Filler
Classification Name and Reference:	Unclassified
Device Product Code and Panel Code:	Orthopedics/87/MQV

I. DEVICE INFORMATION

A. INTENDED USE

JAX™ is indicated only for bony voids or gaps that are not intrinsic to the stability of the bony structure. JAX™ is indicated to be gently packed into bony voids or gaps of the skeletal system, (*i.e.*, the extremities, spine, and pelvis). These defects may be surgically created osseous defects or osseous defects created from traumatic injury to the bone. JAX™ provides a filler that is resorbed and is replaced with bone during the healing process. Because JAX™ is biodegradable and biocompatible, it may be used at an infected site.

B. DEVICE DESCRIPTION

JAX™ is a single-use bone void filler consisting of two components: medical grade calcium sulfate based granules and hydrogel, used as a handling medium. The biodegradable, radiopaque interlocking granules are resorbed in approximately 30-60 days when used according to labeling.

This product is supplied sterile in quantities of 5, 10, and 20 cc of each component for single patient use.

C. SUBSTANTIAL EQUIVALENCE INFORMATION

The intended use, base materials, select device performance and characterization properties, and use of a handling medium with Jax™ are substantially equivalent to those found in one or more of the following predicate products:

- Osteoset™ Pellets (K963587, K963562)
- Synthes Calcium Sulfate Bone Void Filler Pellets (K002362)
- Biogeneration's Profusion Bone Graft Substitute (K973704)
- Encore Orthopedics' Stimulan Calcium Sulfate Bone Void Filler (K982663)
- Howmedica Osteonics Corporation's Calcium Sulfate Pellet (K001559)
- Wright Medical's Allomatrix Demineralized Bone Matrix putty (regulated as a tissue product per 21 CFR 1270)
- Osteotech's Grafton Demineralized Bone Matrix putty (regulated as a tissue product per 21 CFR 1270)

Although Jax™ is not identical to the above stated predicate competitive products, any differences that may exist do not significantly affect the safety and effectiveness of the components.

D. CLAIMS

The following marketing claims will be made for Jax™:

1) ***Advanced Bone Void Filler***
2) ***Material maintains handling characteristics up to 30 minutes after mixing***

E. SUMMARY OF TECHNOLOGICAL COMPARISON

The safety and effectiveness of Jax™ is adequately supported by the substantial equivalence information, materials data, and testing results provided within this Premarket Notification.

The intended use, base material of the granules, select performance properties, and use of a handling medium of the Jax™ product are substantially equivalent to commercially available predicate products. The unique shape, manufacturing process, and addition of a hydrogel as a handling medium are adequately supported by the substantial equivalence information, materials data, and testing results provided within this Premarket Notification. Such information was generated per data requirements outlined in the *Draft Guidance Document for the Preparation of Premarket Notifications [510(k)] Applications for Orthopedic Devices*, dated September 5, 1996.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 2 5 2003

Ms. Kim P. Kelly, MS
Smith & Nephew, Inc.
Orthopaedic Division
1450 Brooks Road
Memphis, TN 38116

Re: K010555
Trade/Device Name: JAX Bone Void Filler
Regulatory Class: Unclassified
Product Code: MQV
Dated: November 26, 2002
Received: November 27, 2002

Dear Ms. Kelly:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4659. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

for Mark N. Melkerson

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K010555

Device Name: ***Jax™***

Indications for Use:

JAX Bone Void Filler is indicated only for bony voids or gaps that are not intrinsic to the stability of the bony structure. JAX are indicated to be gently packed into bony voids or gaps of the skeletal system, (*i.e.*, the extremities, spine, and pelvis). These defects may be surgically created osseous defects or osseous defects created from traumatic injury to the bone. JAX Bone Void Filler provides a filler that resorbs and is replaced with bone during the healing process. Because JAX Bone Void Filler is biodegradable and biocompatible, it may be used at an infected site.

Concurrence of CDRH, Office of Device Evaluation

Prescription Use ✓ OR (Per 21 CFR 801.109) Over-The Counter Use _____

for Mark N Milhouse

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K010555